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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,409	01/18/2002	Susumu Maruo	Q68143	2146

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,409	MARUO ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of Applicant's Arguments/Remarks and the request for extension of time (1 month-granted), both filed 11/23/04 and the Information Disclosure Statement (IDS) filed 08/18/04 is acknowledged.

Claims 1, 4-8 and 11-12 are pending. No amendments to the claims have been made. Claims 1, 4-8 and 11-12 remain rejected.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 08/18/04 was filed after the mailing date of the Non-Final Office Action on 07/27/04. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4-8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda *et al.* (US Pat. No. 5, 045,553) in view of Woo *et al.* (US Pat. No. 6,455,067 B1).

Ueda *et al.* teach a pharmaceutical composition for percutaneous drug absorption and percutaneous drug absorption promoter comprising a patch preparation comprising a support and a gel (ointment) wherein the gel is coated over the aluminum support in an amount or 38.3 mg

per cm^2 and the thickness of the ethylene vinyl acetate (EVA) support film is 50 microns (see reference col. 7, lines 15-20 – Example 12). The gel patch preparation can further include an acrylic adhesive layer on the film (col. 7, lines 15-45). Ueda et al. teach that the pharmaceutical composition can be administered in various dosage forms. When the composition is in the form of a patch, the composition is spread over a support member (col. 3, lines 43-55). The composition may also be made up into ointments, such as Macrogol ointments, FAPG ointments, hydrophilic ointments, absorptive ointments, Carbopol gel ointments, etc (col. 3, lines 64-68). It is also possible to fill the composition in an appropriate container (to prevent adherence to clothes) and attach the container to the skin so that the composition can come into contact therewith or to coat a support member (as in tape preparations) with the composition to a certain thickness and apply the whole to the skin (col. 4, lines 9). Furthermore, the composition can be made up into patches, for example, by spreading the composition over an appropriate support member (i.e., made of aluminum), and if necessary sealing with an absorption promoter film such as ethylene-vinyl acetate copolymer film (col. 4, lines 10-20). The Examples on cols. 7-9 further demonstrates the use of patch preparations comprising a support member and a gel (ointment) in various percentages, which read on the applicant's instantly claimed ranges.

Ueda *et al.* while teaching a pharmaceutical composition for percutaneous drug absorption and percutaneous drug absorption promoter comprising a patch preparation comprising a support and a gel (ointment) wherein the gel is coated over the aluminum support in an amount or 38.3 mg per cm^2 and the thickness of the ethylene vinyl acetate (EVA) support film is 50 microns (col. 7, lines 15-20 – Example 12), do not explicitly teach the degree of water vapor permeability of the support. It would have been obvious to one of ordinary skill in the art

at the time the invention was made to determine suitable amounts or ranges of water vapor permeability through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters. Moreover, generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claims are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Ueda *et al.* are lacking in the sense that they do not explicitly teach a support material comprising a copolymer of vinyl acetate and acrylic acid.

Woo *et al.* teach a transdermal patch comprising a synthetic polymer of *polyvinyl acetate-acrylic acid copolymer* used for strengthening the water retention, the processing and plasticity of the patch. The patch also contains various ointments, gels and support materials made of fabric cloth. The patch provides excellent dermal absorption and good skin adhesion without skin irritation (see reference column 6, lines 5-19); (col. 5, lines 3-13); (col. 6, lines 25-37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined reference teachings of Woo *et al.* within Ueda *et al.* for the teaching of vinyl acetate/acrylic acid copolymers because Woo *et al.* teach a transdermal patch comprising a synthetic polymer of polyvinyl acetate-acrylic acid copolymer which functions to provide strengthening of water retention, processing and plasticity of the patch without

influencing the effects of the patch and similarly Ueda *et al.* teach a patch preparation comprising absorption promoting films such as ethylene-vinyl acetate copolymer film, support materials, ointments and gels contained in the patch. The expected result would be an effective skin patch with improved strengthening, processing and plasticizing capabilities.

Response to Arguments

Applicant's arguments filed 11/23/04 have been fully considered but they are not persuasive.

Firstly, Applicant requested a signed copy of the Form PTO/SB/08 filed with the Information Disclosure Statement of 8/18/04. The Examiner has considered, initialed and signed the PTO Form, which will be submitted with this Office Action.

Secondly, Applicant argued regarding the 35 U.S.C. §103(a) rejection of Claims 1, 4-8, 11 and 12 over Ueda et al. (US '553) in view of Woo et al. (US '067) stating, "Woo et al. discloses an external patch specifically for a non-steroidal anti-inflammatory drug. On the other hand, Ueda et al. discloses a patch preparation for a dihydropyridine compound as an active ingredient. The dihydropyridine compound in Ueda et al. is not a non-steroidal anti-inflammatory drug as required in Woo et al. and thus one of ordinary skill in the art would not have been motivated to combine the references."

Applicant's arguments have been thoroughly considered, but were not persuasive. Arguments directed to the distinctions of the drugs provided in each of the references are not persuasive because no drug has been claimed in the instant invention. The instant claims are completely silent as to the drug preference; therefore, the argument drawn to the teaching of

distinct drug forms by Ueda et al. and Woo et al. is not relevant to the patentability of the instant claims.

Thirdly, Applicant argued, "In Ueda et al., polyvinyl acetate-acrylic acid copolymer was used in the drug formulation, not as the support. In contrast, the patch of the present invention is obtained by using the polyvinyl acetate-acrylic acid copolymer as the support. The support of the patch has no drug formulation. The drug is contained in the ointment."

Applicant's arguments have been thoroughly considered, but were not persuasive. The primary reference of Ueda et al. teaches an ethylene-vinylacetate (EVA) on an aluminum support. Column 4 of Ueda et al. describes an aluminum cloth in which ointment is placed, followed by an EVA layer.

Lastly, Applicant argued, "Woo et al. does not disclose or suggest that the vinyl acetate-acrylic acid copolymer is cross-linked."

Applicant's arguments were not persuasive since there is no claim that requires cross-linking of the vinylacetate-acrylic acid copolymer because the claims permit 0% of the additional ingredients.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh H.N.S.

Patent Examiner

Art Unit 1615

March 02, 2005

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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